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Carl Zeiss Jena GmbH, Ophthalmic Instruments Division

VISULAS 532s - Special 510(k) – Device Modification Summary

Name of Unmodified Device:	ZEISS-DIODE PUMPED SOLID STATE LASER
Name of Modified Device:	VISULAS 532s
Common or Usual Name:	OPHTHALMIC SURGICAL LASER
Classification Name:	LASER INSTRUMENT, SURGICAL, POWERED
Product Code:	GEX
Submitter:	Carl Zeiss Inc. One Zeiss Drive Thornwood, NY 10594, USA Tel.: (914) 681 7761 Fax: (914) 681 7418
Contact Person:	Kenneth M. Nicoll
Date Prepared:	October 05, 2001

Intended Use

The Zeiss-Diode Pumped Solid State Laser (DPSSL) as well as now the modified device renamed as VISULAS 532s is intended for use in photocoagulating ocular tissues in the treatment of diseases of the eye.

The laser energy is delivered via either transpupillary delivery or intraocular ENDO probe delivery.

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Device Modification

The VISULAS 532s laser represents an improved version of the predicate Zeiss-Diode Pumped Solid State Laser (K925642).

The improvement includes the following 2 modifications, which are detailed introduced in the Special 510(k) – Device Modification description:

- In addition to the known laser slit lamp, the slit lamp adapter VISULINK 532/U or the Laser Indirect Ophthalmoscope LIO 532 may be used now as a laser application system.
- Laser console and user interface were improved to allow operation, setting, and monitoring of the different laser treatment procedures.

Conclusion

The introduced side by side comparisons of the VISULAS 532s laser system versus the predicate Zeiss-Diode Pumped Solid State Laser as approved with the notification K925642 indicate that both devices are virtually identical with exception of minor variations which are detailed introduced.

Also the additional applied delivery systems VISULINK 532/U and the LIO 532 are very similar to the already used previously cleared devices/accessories. In addition the delivery systems do not refer to any other claims compared with the approved indications for use.

Thus the described device modification do not raise any new questions for safety and efficacy and in the summary of the reviewed similarities and differences between the compared devices/accessories has to be concluded that the VISULAS 532s may be applied by the surgeon after the modification in a more state of the art way.

Finally the renaming of the Zeiss-Diode Pumped Solid State Laser to VISULAS 532s does not affect any question for safety and efficacy. The new name is caused by the marketing strategy of the Carl Zeiss Jena GmbH, Ophthalmic Instruments Division to use a concerted recognizable device name which distinguishes the laser treatment devices by the applied laser wavelength.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Kenneth M. Nicoll
Carl Zeiss, Inc.
One Zeiss Drive
Thornwood, New York 10594

Re: K013402
Trade Name: Visulas 532S
Regulation Number: 878.4810
Regulation Name: Laser Instrument, Surgical, Powered
Regulatory Class: Class II
Product Code: GEX
Dated: October 5, 2001
Received: October 15, 2001

Dear Mr. Nicoll:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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510(k) Number (if known): _____

Device Name: **VISULAS 532s**

Indication for Use: The VISULAS 532s laser is intended for use in photocoagulating ocular tissues in the treatment of diseases of the eye.

The laser energy is delivered via either transpupillary, delivery or intraocular endoprobe delivery.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K013402